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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,855	02/27/2002	Evan C. Unger	UNGR-1632	8641
23377 7590 02/08/2007 WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891			EXAMINER SOROUSH, LAYLA	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/08/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/084,855	UNGER	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 47, 49-51 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 47, 49-51, and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 1, 2006 has been entered. Claims 1, 47, 49-51, and 55 are pending.

See rejections below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 47, 49-51, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ottoboni et al US Patent 6,193, 951 in view of Grinstaff et al US Patent 5,498,421, Unger et al and Hirota US Patent 4,960,595.

Ottoboni teaches bi-layered shell microspheres containing an outer shell and an inner shell, wherein the outer layer will be a biologically compatible material and the inner layer will be a biodegradable polymer tailored to form a core that contains a gas and can further provide drug delivery properties (see col 2, lines 44-67). Ottoboni

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teaches that the inner layer comprise an organic liquid core that falls within the limitation of the instantly recited oil. (see col 8, lines 1-67). Otobboni fails to specifically employ a lipid component such as a phosphatidic acid in his microspheres. Grinstaff teaches that polymeric shells may be modified with phospholipids to form a stabilized lipid containing microspheres (see claim 26). In fact, Grinstaff teaches similar microspheres as Ottoboni, except that it comprise a biologic agent, a polymeric shell encapsulating a perfluorocarbon gas. (see col 12, lines 10-40; example 13, 35-37, claims 1, 12-13). Grinstaff only fails to articulate the use of a phosphatidic acid as a lipidic moiety.

Unger teaches delivery systems comprising gas filled liposomes containing a bioactive agent, and an oil (see abstract, col 21, line 20-col 22, lines 9-67). The delivery systems of Unger contains one or more phospholipids selected from group phosphatidic acid, phosphatidylcholine, phosphatidylethanolamines, perfluorocarbon, and a suitable oils such as glyceryl monostearate, corn oil, olive oil, mineral oil etc... (see col 13, lines 30-45; col 8, lines 10-21; 32, lines 55-65; col 33, lines 5-10). Unger teaches phosphatidic acid containing microspheres.

Hirato explicitly says that phosphatidic acid is an auxiliary material that stabilizes dispersions of lipidic microspheres (see col 3, lines 20-44).

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to employ at least one lipidic components of Unger in the microspheres of Ottoboni to provide effective drug delivery systems, because as described by Grinstaff, polymeric shells can be modified to contain phospholipids and as evidenced by Unger and as described by Hirato, phosphatidic acid improves the stability of such

microspheres. One of ordinary skill in the art would have been motivated to do such modifications because, as described by Grinstaff, polymeric shells and their phospholipids modified analogs are art recognized functional equivalents. Further, the use of phosphatidic acid is conventionally practiced to improve the stability of such microspheres. Accordingly, the combination of the cited references render the instant claims obvious as it teaches all elements of the instant claims.

Response to Arguments

Applicant's arguments filed on December 1, 2006 have been considered.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Ottoboni et al US Patent 6,193, 951, Grinstaff et al US Patent 5,498,421, Unger et al and Hirota US Patent 4,960,595 all teach microspheres for therapeutic purposes all of which in combination provide motivation to produce the claimed invention (see rejections stated above). Additionally, Examiner respectfully reiterates, it would have been obvious to one of ordinary skill in the art at the time of invention to employ at least one lipidic components of Unger in the microspheres of Ottoboni to provide effective drug delivery systems, because as described by Grinstaff, polymeric shells can be modified to contain

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phospholipids and as evidenced by Unger and as described by Hirato, phosphatidic acid improves the stability of such microspheres. One of ordinary skill in the art would have been motivated to do such modifications because, as described by Grinstaff, polymeric shells and their phospholipids modified analogs are art recognized functional equivalents. Further, the use of phosphatidic acid is conventionally practiced to improve the stability of such microspheres. Accordingly, the combination of the cited references render the instant claims obvious as it teaches all elements of the instant claims.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. L. L.